



DOCKET NO.: ALZA-0129

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Guohua Chen, et al.

Application No.: 10/699,521

Filing Date: October 31, 2003

For: SUSTAINED RELEASE DOSAGE FORMS OF ANESTHETICS FOR PAIN

Confirmation No.:

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: February 5, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

*Karen M. Whitney*

TYPED NAME: Karen M. Whitney  
REGISTRATION NO.: 52,355

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

## EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - ☒ Copies of references **1 thru 9 and 14 thru 168** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No.10/606,969, filed **June 25, 2003**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: *February 5, 2004*

*Karen M. Whitney*  
\_\_\_\_\_  
**Karen M. Whitney**  
Registration No. 52,355

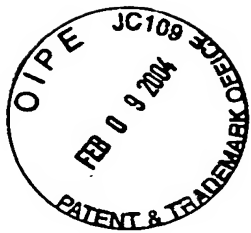
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>ALZA-0129</b>	Application No. <b>10/699,521</b>
	Applicant <b>Guohua Chen, et al.</b>	
	Filing Date <b>October 31, 2003</b>	Group <b>Not Yet Assigned</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	<b>1</b>	Cleland, J. L. "Injectable Gels for Local and Systemic Delivery of Proteins," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.
	<b>2</b>	Blanco, M. D. et al. "Bupivacaine-loaded comatrix formed by alumin microspheres included in a poly(lactide-coglycolide) film: in vivo biocompatibility and drug release studies," <u>Biomaterials</u> , Vol. 20, pp.1919-1924, 1999.
	<b>3</b>	Duenas, E. et al. "Sustained Delivery of rhVEGF from a Novel Injectable Liquid, Plad" <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.
	<b>4</b>	Guevello, P. Le at al. "High-performance liquid chromatographic determination of bupivacaine in plasma samples for biopharmaveutical studies and application to seven other local anaesthetics," <u>Journal of Chromatography</u> , Vol. 622, pp. 284-290, (1993).
	<b>5</b>	Garry, M. G. et al. "Evaluation of the efficiency of a bioerodible bupivacaine polymer system on antinociception and inflammatory mediator release," <u>Pain</u> , vol. 82, pp. 49-55, 1999.
	<b>6</b>	Lambert, W. J. at al. "Development of an in situ forming bidegradable poly-lactide-co-glycolide system for controlled release of proteins," <u>Journal of Controlled Release</u> , Vol. 33, pp. 189-195 (1995).
	<b>7</b>	Okumu, F. W. et al. "Sustained Delivery of Growth Hormone from a Novel Injectable Liquid, Plad," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.
	<b>8</b>	Okumu, F. W. et al. "Evaluation of the Saber™ Delivery System for Sustained Release of Growth Hormone – Formulation Design and <i>In Vivo</i> Assessment," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.
	<b>9</b>	Philip, B. K. et al. "The Economic Impact of Opioids on Postoperative Pain Management," <u>Journal of Clinical Anesthesia</u> , Vol. 14, pp. 354-364, 2002.
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	<b>10</b>	Trieger, N. et al., "Bupivacaine and Post-Operative Analgesics in Oral Surgery", <i>Anesthesia Progress</i> , <b>1979</b> , 20- 23
	<b>11</b>	USP XXII (NFXVII), <i>The United States Pharmacopeial Convention, Inc., Bupivacaine</i> , <b>1990</b> , 193-196
	<b>12</b>	Castillo, J. et al., " <i>Glucocorticoids Prolong Rat Sciatic Nerve Blockade in Vivo from Bupivacaine Microspheres</i> ", <i>Anesthesiology</i> , <b>1996</b> , 85, 1157-1166
	<b>13</b>	P.A.Moore, "Long Acting Local Anesthetic: A Review of Clinical Efficacy in Dentistry", <i>Compend. Cont. Ed. Dent.</i> , <b>1990</b> , 11, 22-30
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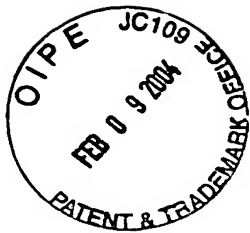
**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	14	3,797,492	03/19/74	Place	128	260
	15	3,923,939	12/02/75	Baker	264	49
	16	3,987,790	10/26/76	Eckenhoff, et al.	128	260
	17	4,008,719	02/22/77	Theeuwes, et al.	128	260
	18	4,443,340	04/17/84	May, et al.	210	697
	19	4,586,559	02/04/86	Nuwayser, et al.	427	3
	20	4,623,588	11/18/86	Nuwayser, et al.	428	402.24
	21	4,668,506	05/26/87	Bawa	424	429
	22	4,708,861	11/24/87	Popescu, et al.	424	1.1
	23	4,711,782	12/08/87	Okada, et al.	424	455

**FOREIGN PATENT DOCUMENTS**

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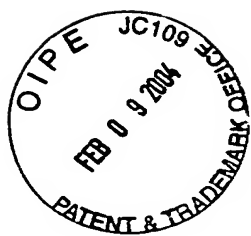
Examiner Initial		Document No.	Date	Name	Class	Subclass
	24	4,713,244	12/15/87	Bawa, et al.	424	429
	25	4,853,218	08/01/89	Yim, et al.	424	85.7
	26	4,865,845	09/12/89	Eckenhoff, et al.	424	424
	27	4,866,050	09/12/89	Ben-Amoz	514	179
	28	4,931,279	06/05/90	Bawa, et al.	424	427
	29	4,938,763	07/03/90	Dunn, et al.	604	891.1
	30	4,985,404	01/15/91	Mitchell, et al.	514	6
	31	5,019,400	05/28/91	Gombotz, et al.	424	497
	32	5,057,318	10/15/91	Magruder, et al.	424	438
	33	5,059,423	10/22/91	Magruder, et al.	424	438

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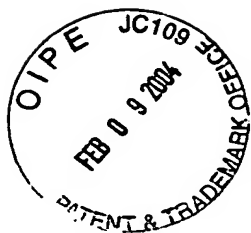
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	34	5,061,492	10/29/91	Okada, et al.	424	423
	35	5,077,033	12/31/91	Viegas, et al.	514	668
	36	5,085,866	02/04/92	Cowsar, et al.	424	481
	37	5,112,614	05/12/92	Magruder, et al.	424	422
	38	5,137,727	08/11/92	Eckenhoff, et al.	424	422
	39	5,151,093	09/29/92	Theeuwes, et al.	604	892.1
	40	5,181,914	01/26/93	Zook	604	307
	41	5,209,746	05/11/93	Balaban, et al.	604	892.1
	42	5,234,692	08/10/93	Magruder, et al.	424	473
	43	5,234,693	08/10/93	Magruder, et al.	424	473

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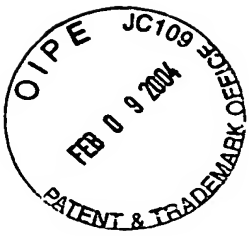
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	44	5,242,910	09/07/93	Damnj	514	152
	45	5,252,318	10/12/93	Joshi, et al.	424	78.04
	46	5,278,201	01/11/94	Dunn, et al.	523	133
	47	5,279,608	01/18/94	Cheikh	604	892.1
	48	5,308,348	05/03/94	Balaban, et al.	644	891.1
	49	5,310,865	05/10/94	Enomoto, et al.	528	361
	50	5,324,519	06/28/94	Dunn, et al.	424	426
	51	5,300,295	08/05/94	Viegas, et al.	424	427
	52	5,336,057	08/09/94	Fukuda, et al.	417	395
	53	5,330,452	07/19/94	Zook	424	448

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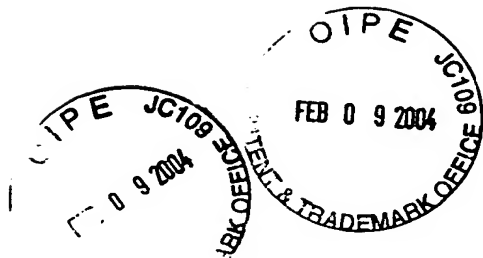
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Examiner Initial		Document No.	Date	Name	Class	Subclass
	54	5,340,614	08/23/94	Perman, et al.	427	2.24
	55	5,342,627	08/30	Chopra, et al.	424	473
	56	5,415,866	05/16/95	Zook	424	448
	57	5,540,912	07/30/96	Roorda, et al.	424	422
	58	5,441,732	08/15/95	Hoeg, et al.	424	78.04
	59	5,447,725	09/05/95	Damani, et al.	424	435
	60	5,456,679	10/10/95	Balaban, et al.	604	892.1
	61	5,487,897	01/30/96	Polson, et al.	424	426
	62	5,540,912	07/30/96	Roorda, et al.	424	422
	63	5,543,156	08/06/96	Roorda, et al.	424	484

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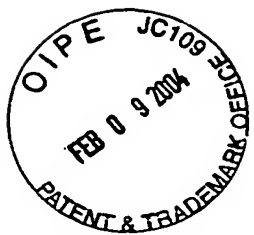
Examiner Initial		Document No.	Date	Name	Class	Subclass
	64	5,556,905	09/17/96	Frappier, et al.	524	311
	65	5,571,525	11/05/96	Roorda, et al.	424	426
	66	5,787,175	12/24/96	Viegas, et al.	424	427
	67	5,599,534	02/04/97	Himmelstein, et al.	424	78.04
	68	5,599,552	02/04/97	Dunn, et al.	424	423
	69	5,610,184	03/11/97	Shahinian, Jr.	514	540
	70	5,618,563	04/08/97	Berde, et al.	424	501
	71	5,620,700	04/15/97	Berggen, et al.	424	435
	72	5,651,986	07/29/97	Brem, et al.	424	484
	73	5,654,010	08/05/97	Johnson, et al.	424	502

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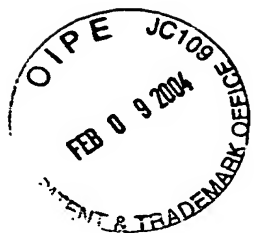
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Examiner Initial		Document No.	Date	Name	Class	Subclass
	84	5,747,058	05/05/98	Tipton, et al.	424	337
	85	5,747,060	05/05/98	Sackler, et al.	424	426
	86	5,759,563	06/02/98	Yewey, et al.	424	426
	87	5,760,077	06/02/98	Shahinian Jr.	514	540
	88	5,766,637	06/16/98	Shine, et al.	424	497
	89	5,780,044	07/14/98	Yewey, et al.	424	426
	90	5,783,205	07/21/98	Berggren, et al.	424	426
	91	5,804,212	09/08/98	Illum	424	434
	92	5,849,763	12/15/98	Bardsley, et al.	514	445
	93	5,910,502	06/08/99	Gennery	514	330

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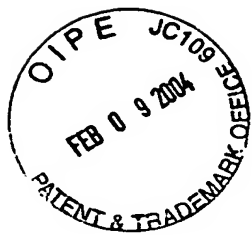
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	94	5,922,340	07/13/99	Berde, et al.	424	426
	95	5,942,241	08/24/99	Chasin, et al.	424	426
	96	5,955,479	09/21/99	Bardsley, et al.	514	330
	97	5,958,443	09/28/99	Viegas, et al.	424	427
	98	5,972,326	10/26/99	Galin, et al.	424	78.04
	99	5,972,366	10/26/99	Haynes, et al.	424	422
	100	5,990,194	11/23/99	Dunn, et al.	523	113
	101	5,919,835	07/06/99	Domb, et al.	523	113
	102	6,004,295	12/21/99	Langer, et al.	604	164
	103	6,046,187	04/04/00	Berde, et al.	514	180

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	104	6,050,986	04/18/00	Hektner	604	508
	105	6,086,909	07/11/00	Harrison, et al.	424	430
	106	6,103,266	08/15/00	Tapolski, et al.	424	484
	107	6,106,301	08/22/00	Merril	434	262
	108	6,117,425	09/12/00	McPhee, et al.	424	94.64
	109	6,120,789	09/19/00	Dunn	424	426
	110	6,120,804	09/19/00	Drizen, et al.	424	488
	111	6,129,933	10/10/00	Oshlack, et al.	424	495
	112	6,130,200	10/10/00	Brodbeck, et al.	514	2
	113	6,136,334	10/24/00	Viegas, et al.	424	427

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	114	6,143,314	11/07/00	Chandrasekhar, et al.	424	426
	115	6,193,991	02/27/01	Shukla	424	426
	116	6,193,994	02/27/01	Lee, et al.	424	444
	117	6,197,327	03/06/01	Harrison, et al.	424	430
	118	6,214,387	04/10/01	Berde, et al.	424	501
	119	6,217,911	04/17/01	Vaung, et al.	424	501
	120	6,238,702	05/29/01	Berde, et al.	424	489
	121	6,248,345	06/19/01	Goldenheim, et al.	424	426
	122	6,255,502	07/03/01	Penkler, et al.	552	549
	123	6,261,547	07/17/01	Bawa, et al.	424	78.04

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Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>ALZA-0129</b>	Application No. <b>10/699,521</b>
	Applicant <b>Guohua Chen, et al.</b>	
	Filing Date <b>October 31, 2003</b>	Group <b>Not Yet Assigned</b>

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	126	6,352,667	03/05/02	English	264	328.17
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	128	6,372,245	04/16/02	Bowman, et al.	424	427
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	130	6,395,293	05/28/02	Polson, et al.	424	426
	131	6,403,057	06/11/02	Schneider, et al.	424	9.52
	132	6,417,201	07/09/02	Bardsley, et al.	514	330
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Docket No.  
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**October 31, 2003**

Group  
**Not Yet Assigned**

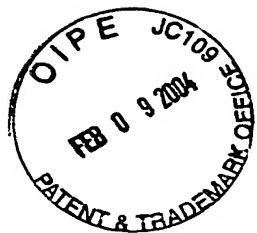
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	136	6,451,346	09/17/02	Shah	424	486
	137	6,543,081	03/18/03	Goldenheim, et al.	424	426
	138	2001/0004644 A1	06/21/01	Levin	514	646
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	Applicant <b>Guohua Chen, et al.</b>	
	Filing Date <b>October 31, 2003</b>	Group <b>Not Yet Assigned</b>

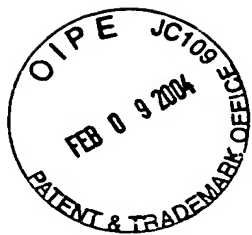
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	<b>152</b>	2002/0054915 A1	05/09/02	Goldenheim, et al.	424	497
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	<b>156</b>	WO 95/13799		PCT		
	<b>157</b>	WO 98/27962		PCT		
	<b>158</b>	WO 98/27963		PCT		
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